

Remarks

Status of the Claims

Claims 1-52 are pending in this application. Claims 1, 18, 31, and 44 are amended herein to include as a feature, that the pad is non-adhesive. Support for the amendment of claims 1, 18, 31, and 44 can be found throughout the specification and the claims as originally filed, and specifically in the specification at page 2, lines 4-6, page 2, line 10, page 3, line 4, Figure 1 and the brief description thereof found at page 3, and original claims 2 and 33. Claim 52 is amended to correct an obvious clerical error. No new matter is introduced by these amendments.

Reconsideration of the rejection of the claims is respectfully requested.

Information Disclosure Statement

Applicant notes the references listed on the first page of the IDS submitted February 17, 2004, were not signed by the Examiner. It is Applicant's understanding that this is a clerical error, and that the references were considered. To ensure that the record is clear, Applicant has provided an additional copy of the PTO-1449 form submitted on February 17, 2004. Applicant respectfully requests that the Examiner initial and date this copy of the PTO-1449 to make the record clear that the listed references were considered.

Rejections under 35 U.S.C. § 102

Claims 1-43 and 49-52 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cox (U.S. Patent No. 5,695,484). Applicant respectfully disagrees. However, solely in the interest of advancing prosecution, Applicant has amended the independent claims (claims 1, 18, and 31) to include the claim feature that the pad is "non-adhesive." This feature is neither taught nor suggested by Cox and there is no anticipation. The pad taught by Cox must include an adhesive as is definitively stated in column 1, lines 31-32, which recites that "[t]he present invention in its broadest terms, comprises a pad having a biocompatible adhesive on one side [emphasis added]." All of the embodiments taught by Cox are adhesive pads. Thus, Cox cannot possibly anticipate claims 1-43 and 49-52, which all include the feature that the pad is "non-adhesive."

Cox also does not render claims 1-43 and 49-52 obvious. Cox only discloses an adhesive pad that "not only provides the seal preventing the leakage of discharges from the anal opening from beyond the anal patch, but the adhesive coating also maintains the anal patch in place during usage." Column 4, lines 20-23. Moreover, Cox also states that "[t]he adhesive coating must be relatively strong." Column 4, lines

23-24. It would not be obvious to eliminate the adhesive because that would disrupt the “seal preventing the leakage of discharges from the anal opening,” as Cox only teaches pads that have relatively strong adhesives serving to prevent leakage. The only means of attaching the pad to the subject is by adhering it to the subject, then peeling the adherent soiled patch off the subject following use (Cox, column 2, line 34-41). Furthermore, any modification of the Cox patch in which the patch was rendered non-adhesive would frustrate or destroy its purpose and function, which is to provide an adhesive seal to prevent leakage. It would not be obvious to modify Cox in such a way that it would contravene the explicit teaching of Cox that strong adhesive *must* be present on the pad to adhere it to the user’s body for its intended purpose. Also, if the externally applied patch of Cox were rendered non-adhesive, the patch would fall off and be rendered inoperative, because the Cox patch is only held in place by the adhesive. It is not frictionally retained between the buttocks as in the claimed method.

In view of the amendments made herein, Applicant requests that the rejection of claims 1-43 and 49-52 be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 44-48 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cox. Claims 44-48 include the feature that the pad is “non-adhesive.” As discussed previously, Cox does not teach this feature. In addition, Cox teaches that an adhesive is a required element of the disclosed pads. Thus, any modification that renders the pad of Cox non-adhesive would be contrary to the teaching of Cox. For at least this reason no *prima facie* case of obviousness has been established with respect to claims 44-48 and they are allowable. Applicant requests that the rejection be withdrawn.

Claims 16, 17, 29, and 30 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cox in view of Okuda (U.S. Patent No. 4,920,045). The Office action asserts that it would be obvious to modify the pad disclosed by Cox to perform a diagnostic test on fecal material, because Okuda discloses that occult blood can be detected in feces. Claims 16, 17, 29, and 30 include the feature that the pad is “non-adhesive.” Cox does not teach this feature and in fact teaches against it. This feature also is not taught or suggested by Okuda. Thus, the asserted combination of Cox and Okuda does not teach or suggest each and every feature of claims 16, 17, 29, and 30. For at least the above reasons, the Office has not presented a *prima facie* case of obviousness with respect to claims 16, 17, 29, and 30. Therefore, these claims are allowable, and Applicant requests that the rejection be withdrawn.

Dependent Claims

All rejected dependent claims depend from a rejected independent claim and are allowable for the same reasons as the corresponding independent claim. Each of the dependent claims is further allowable in view of the patentable combination of features recited in such dependent claim.

Claim 4 specifies that the “pad has a uniform cross-section along its entire length or is tapered along its length.” None of the embodiments of the device disclosed by Cox have a uniform cross section or are tapered along their length. The embodiments disclosed by Cox have a cross section that changes from small to large to small moving down the length of the device. This device can not be described as either having a uniform cross section across its length, which describes a cross section does not change as a function of length, or tapering, which describes a shape that becomes smaller as a function of length. For this additional reason, the cited references do not teach all of the element present in claim 4. Claim 4 is neither anticipated nor obvious in view of the cited references. In addition, the Office has not provided any reason why this claim is rejected.

Claim 14 specifies that the “tapered leading edge is positioned against the anal orifice, and a remainder of the pad has a width which is wider than a normal anatomic intergluteal space, such that the remainder of the pad is *frictionally* engaged and retained by opposing gluteals [emphasis added].” The device disclosed by Cox is secured in place by an adhesive, not by frictional engagement of the pad between the gluteals of the subject. Thus, Cox does not teach all of the features present in claim 14. This deficiency as not made up by Okuda. For at least this additional reason claim 14 is neither anticipated nor obvious in view if the cited references.

Claim 20 includes the feature, “wherein the pad is elongated and has a uniform cross-section along its entire length, or is tapered along its length.” As discussed above with respect to claim 4, this feature is neither taught nor suggested by the cited references. For at least this additional reason the cited references do not anticipate or render claim 20 obvious.

Claim 21 recites that the pad, “when placed in the intergluteal space, extends external to the anal orifice and a vaginal opening to absorb leakage from the vagina in addition to leakage from the anus.” Neither Cox nor Okuda mention absorbing leakage from the vagina. These references do not teach, alone or together, all of the features present in claim 21 and it is allowable.

Claim 28 is allowable for the same reasons that claim 14 is allowable.

Conclusion

The references cited in the Office action do not teach or suggest all of the limitations present in the claims and thus cannot anticipate the claims. A *prima facie* case of obviousness has not been established by the Office action because the claimed subject matter is not disclosed or suggested by the cited references. In addition, any modification of the cited references to produce the invention as claimed would be opposed to the teaching of the primary reference (Cox). In view of the amendments and arguments presented, Applicant requests that the rejections of the claims be reconsidered and withdrawn. Applicant believes that the claims are in condition for allowance, and a notice to this effect is requested. If any matters remain before a Notice of Allowance is issued, the Examiner is invited to telephone the undersigned at the telephone number below to discuss the case.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Ian J. Griswold/
Ian J. Griswold, Ph.D.
Registration No. 57,338